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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,679	02/18/2004	Rohit Duggal	PC25446A	5221
28940	7590	08/28/2006	EXAMINER	
PFIZER INC 10555 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			OLSON, ERIC	
			ART UNIT	PAPER NUMBER

1623  
DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/782,679	<b>Applicant(s)</b> DUGGAL ET AL.	
	<b>Examiner</b> Eric S. Olson	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

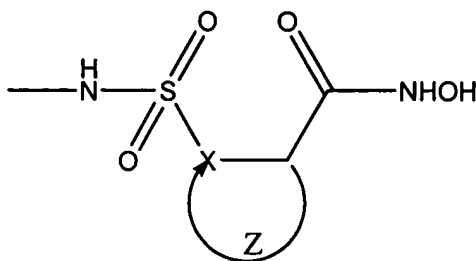
- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### Detailed Action

This application claims benefit of provisional application 60/448253, filed February 18, 2003. Claims 1-17 are pending in this application and subject to restriction herein. Applicant's preliminary amendment submitted March 15, 2004 is acknowledged wherein the specification is amended.

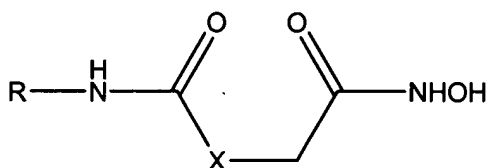
Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 9-10, drawn to a method of decreasing HCV viral replication comprising contacting an HCV polymerase with a therapeutically effective amount of a compound of formula I or II as defined in the claims, classified in class 514, subclass 602, 603, or 604, for example.
- II. Claims 11, 12, and 17 in part and 13 and 14 in full, drawn to a method of decreasing HCV viral replication comprising contacting an HCV polymerase with a therapeutically effective amount of a compound of formula III as defined in the claims, classified in class 514, subclass 602, 603, or 604, for example.
- III. Claims 11, 12, and 17 in part and 15-16 in full, drawn to a method of decreasing HCV viral replication comprising contacting an HCV polymerase with a therapeutically effective amount of a compound having formula  $\alpha$  as defined below, classified in class 514, subclass 602, 603, or 604, for example.



Formula  $\alpha$ , X = N or C, Z = a 5 or 6-membered aliphatic ring

- IV. Claims 11, 12, and 17 in part, drawn to a method of decreasing HCV viral replication comprising contacting an HCV polymerase with a therapeutically effective amount of a compound containing a  $\gamma$ -keto-hydroxamate group of formula  $\beta$  as defined below, classified in class 514, subclass 616-623 or 626, for example.



formula  $\beta$ , X = C or N

- V. Claim 11 in part, drawn to a method of decreasing HCV viral replication comprising contacting an HCV polymerase with a therapeutically effective amount of an aromatic hydroxamate or hydroxyurea compound, classified in class 514, subclass 617-624, for example.
- VI. Claims 11 and 12 in part, drawn to a method of decreasing HCV viral replication comprising contacting an HCV polymerase with a therapeutically effective amount of an acyclic aliphatic hydroxamate

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compound not having formula I-III, or containing a substructure of formula  $\alpha$  or  $\beta$ , classified in class 514, subclass 626-629, for example.

Claims 1-8 link inventions I-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the related methods utilize distinct active ingredients. Chemical structures which are similar are presumed to function similarly, while chemical structures which are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of **Application of Papesch, 50 CCPA 1084, 315 F.2s 381, 137 USPQ 43 (CCPA 1963)**, and **In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984)**, chemical structures are patentably distinct where structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure. In the instant case, the structures differ in the presence or absence of different function groups (sulfonamides and amides) and the orientation of those functional groups. For example, the presence of sulfonamides in groups I-III, as opposed to the presence of an amide at the same position in group IV or the absence of such functional groups in groups V-VI is expected to affect the interaction of the compounds with their target. Similarly, the presence of a ring in the compounds of group II is expected to freeze the relative orientation of the hydroxamate and

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sulfonamide groups into one particular orientation. These functional groups are especially significant because the compounds are to be used as matrix metalloprotease inhibitors and their biological activity is expected to depend on their ability to chelate metal ions using these functional groups.

Thus, a reference anticipating or rendering obvious one member will not anticipate or render another obvious. This difference is illustrated by the separate classifications of the active compounds in each group. A chemical structure or name search for more than one of the aforementioned groups in a single application would be unreasonably broad and would require separate searches of the chemical literature for each group and impose an undue search burden on the Office.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as recognized by their different classifications, restriction for examination purposes as indicated is proper.

### **Election of Species**

This application contains claims directed to the following patentably distinct species: A plurality of hydroxamate MMP inhibitors disclosed in instant claims 9-17. The species are independent or distinct because they possess divergent chemical structures.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-8 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103(a) of the other invention.



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Because the above restriction requirement is complex, a telephone call to applicant's agent to request an oral election was not made. (See MPEP 812.01) Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

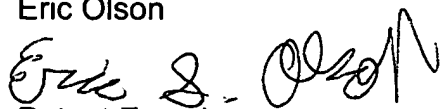
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Eric Olson

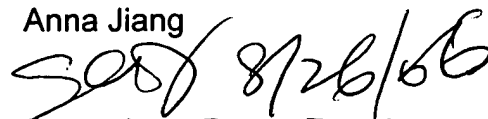
A handwritten signature in black ink, appearing to read "Eric S. Olson".

Patent Examiner

AU 1623

8/23/06

Anna Jiang

A handwritten signature in black ink, appearing to read "S. Jiang" followed by the date "8/26/06".

Supervisory Patent Examiner

AU 1623